

# **Exhibit H**

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1 - - -  
2 :SUPERIOR COURT OF  
3 :NEW JERSEY  
4 IN RE: :LAW DIVISION -  
5 PELVIC MESH/GYNECARE :ATLANTIC COUNTY  
6 LITIGATION :  
7 :MASTER CASE 6341-10  
8 :  
9 :CASE NO. 291 CT  
10  
11 CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF  
12 CONFIDENTIALITY  
13 - - -  
14 May 18, 2012  
15 - - -  
16 Transcript of the deposition of  
17 SEAN M. O'BRYAN, called for Videotaped  
18 Examination in the above-captioned matter, said  
19 deposition taken pursuant to Superior Court Rules  
20 of Practice and Procedure by and before Maryellen  
21 Coughlin, a Certified Realtime Reporter,  
22 Registered Professional Reporter, and Notary  
23 Public for the Commonwealth of Massachusetts, at  
24 the offices of Campbell Campbell Edwards &  
25 Conroy, P.C., One Constitution Center, 3rd Floor,  
Boston, Massachusetts, commencing at 10:05 a.m.

22 - - -  
23 GOLKOW TECHNOLOGIES, INC.  
24 877.370.3377 ph | 917.951.5672 fax  
25 depson@golkow.com

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1       warnings that a patient could be faced with that  
2       are important for the patient.

3           Q.       And to the extent you had input  
4       into the Prolift® IFU drafting process, you  
5       certainly wanted to make sure that any warnings  
6       of any significant potential risks would be  
7       explicitly communicated to the intended or  
8       foreseeable users of the Prolift®, correct?

9           MS. KABBASH: Objection.

10          A.       Sure. I rely on the medical team  
11       to tell me what is significant and what is  
12       important to convey into the instructions for  
13       use, package insert.

14          Q.       When you worked on that project, it  
15       was your understanding from an FDA regulatory  
16       perspective it would not be legitimate to not  
17       include warnings of potentially significant  
18       adverse events based on a decision that the  
19       surgeons would figure that out on their own?

20           MS. KABBASH: Objection.

21          A.       No, that's correct.

22          Q.       Would you turn to Page 22, please.  
23       It's Paragraph D, D.1.3. The question is asked,  
24       "Do the results of the design validation  
25       performed as a result of this change in materials

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1                   A.         Yes, yes.

2                   Q.         Do you know if those were done by  
3                   the TVM or the Prolift® procedure or by other  
4                   procedures?

5                   A.         I can't recall. I'm sorry.

6                   Q.         You were asked by counsel about  
7                   whether or not it was your responsibility to make  
8                   sure adverse events were properly communicated in  
9                   the IFU, and I think you said your responsibility  
10                  to make sure that once medical affairs decided  
11                  that those adverse events belonged, were  
12                  significant enough that they needed to be  
13                  communicated because they were risks associated  
14                  with the Prolift®, you want to make sure that it  
15                  would not be presented in a confusing way,  
16                  correct?

17                  A.         Yes.

18                  Q.         And part of that would be that if  
19                  such a risk was known and was going -- rephrase.

20                           And part of that would be that  
21                  if -- rephrase.

22                           This is the last question of the  
23                  day. And part of that review that you're talking  
24                  about would include making sure that, to the  
25                  extent a risk did need to be included in the IFU,

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1 because, as you said, if it's known by medical  
2 affairs to be a risk connected to the Prolift® it  
3 should be in there, you don't want it to be  
4 presented in a confusing way, and you want it to  
5 be explicitly and clearly set forth, correct?

6 MS. KABBASH: Objection.

7 A. That's a fair assessment, yeah.

8 MR. SLATER: No other questions.

9 MS. KABBASH: I think we're done.

10 THE VIDEOGRAPHER: Person on the  
11 phone any questions?

12 This concludes the May 18th, 2012,  
13 deposition of Sean M. O'Bryan. The number of  
14 tapes used today was 3. We are off the record at  
15 4:59 p.m.

16 (Deposition suspended/concluded  
17 at 4:59 p.m.)

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